PATENT COOPERATION TREATY

From the INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To: GERVASI, Gemma Notarbartolo & Gervasi S.p.A. Corso di Porta Vittoria 9 1-20122 Milan **NOTARBARTOLO & GERVASI ITALIE** CEIVED MAR. 2006

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(PCT Rule 71.1)

Date of mailing (day/month/year)

28.03.2006

Applicant's or agent's file refere 4530PTW/AG/la

International filing date (day/month/year)

Priority date (day/month/year)

IMPORTANT NOTIFICATION

International application No. PCT/EP2004/053251

03.12.2004

03.12.2003

Applicant

MILIOR S.P.A. et al.

- The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary report on patentability and its annexes, if any, established on the international application.
- 2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
- Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the international preliminary examining authority:



European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016

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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

| Applicant's or agent's file reference 4530PTW/AG/la | FOR FURTHER ACTION | N See Form PCT/IPEA/416 | |
|--|--|---|--|
| International application No. PCT/EP2004/053251 | International filing date (dayling 03.12.2004 | onth/year) Priority date (day/month/year) 03.12.2003 | |
| International Patent Classification (IPC) or national classification and IPC A61B5/113, A61B5/0408 | | | |
| | | · | |
| Applicant MILIOR S.P.A. et al. | | | |
| This report is the international pre Authority under Article 35 and tra | eliminary examination report, nsmitted to the applicant acco | established by this International Preliminary Examining ording to Article 36. | |
| 2. This REPORT consists of a total of 6 sheets, including this cover sheet. | | | |
| 3. This report is also accompanied by ANNEXES, comprising: | | | |
| a. Sent to the applicant and t | o the International Bureau) a | total of 2 sheets, as follows: | |
| sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions). | | | |
| beyond the disclosure Supplemental Box. | e in the international application | this Authority considers contain an amendment that goes on as filed, as indicated in item 4 of Box No. I and the | |
| coguence listing and/or ta | bles related thereto, in compl | te type and number of electronic carrier(s)) , containing a uter readable form only, as indicated in the Supplemental the Administrative Instructions). | |
| | | | |
| 4. This report contains indications r | elating to the following items: | : | |
| Box No. I Basis of the op | pinion | · | |
| ☐ Box No. II Priority | | | |
| | | novelty, inventive step and industrial applicability | |
| ☐ Box No. IV Lack of unity of | f invention | | |
| applicability; c | itations and explanations sup | th regard to novelty, inventive step or industrial porting such statement | |
| ☐ Box No. VI Certain docum | | | |
| | s in the international applicati | | |
| ☐ Box No. VIII Certain observ | vations on the international ap | oplication | |
| Date of submission of the demand | Da | ate of completion of this report | |
| 29.09.2005 | 28 | 3.03.2006 | |
| Name and mailing address of the international preliminary examining authority: | | uthorized Officer | |
| European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl | | nüpling, M | |
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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No. PCT/EP2004/053251

| _ | Box No. I Basis of the report | | |
|----|---|--|--|
| | fith regard to the language , this report is based on the international application in the language in which it was ed, unless otherwise indicated under this item. | | |
| | □ This report is based on translations from the original language into the following language, which is the language of a translation furnished for the purposes of: □ international search (under Rules 12.3 and 23.1(b)) □ publication of the international application (under Rule 12.4) □ international preliminary examination (under Rules 55.2 and/or 55.3) | | |
| 2. | Vith regard to the elements* of the international application, this report is based on (replacement sheets which lave been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this eport as "originally filed" and are not annexed to this report): | | |
| | Description, Pages | | |
| | 1-7 | as originally filed | |
| | Claims, Numbers | | |
| | 1-21 | received on 03.10.2005 with letter of 03.10.2005 | |
| | Drawings, Sheets | | |
| | 1/4-4/4 | as originally filed | |
| | ☐ a sequence listing and/or an | y related table(s) - see Supplemental Box Relating to Sequence Listing | |
| 3 | The amendments have resulted in the cancellation of: ☐ the description, pages ☐ the claims, Nos. ☐ the drawings, sheets/figs ☐ the sequence listing (specify): ☐ any table(s) related to sequence listing (specify): | | |
| 4 | had not been made, since they is Supplemental Box (Rule 70.2(c)) the description, pages the claims, Nos. the drawings, sheets/figs the sequence listing (specific any table(s) related to see | s ecify): equence listing <i>(specify)</i> : | |
| | + If item 4 applies So | ome or all of these sheets may be marked "superseded." | |

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)

Yes: Claims

1-21

No:

Claims

Inventive step (IS)

Yes: Claims

Claims

No:

1-21

1-21

Industrial applicability (IA)

Yes: Claims

No: Claims

2. Citations and explanations (Rule 70.7):

see separate sheet

10/581478 *AP3 Rec'd PCT/PTO 01 JUN 2007

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (SEPARATE SHEET)

International application No.

PCT/EP2004/053251

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

D1: PARADISE R ET AL: "Knitted bioclothes for cardiopulmonary monitoring"

D2: GB-A-1 417 394

D3: WIJESIRIWARDANA R ET AL: "Resistive fibre-meshed transducers"

1. Independent claims 1, 16 - 19

1.1

The present application does not meet the requirements of Article 33(3) PCT, because the subject-matter of claims 1, 13 - 19 does not involve an incentive step. The reasons are the following:

Document D1 discloses (the references in parenthesis applying to this document):

Knitted fabric wherein piezoresistive sensors for the monitoring of movement and breathing, electrodes for the monitoring of cardiac activity and breathing, and conductive connections for the transmission of signals are integrated (abstract; figure 2).

1.2

Consequently, the subject-matter of claim 1 differs from D1 in the feature that

said knitted fabric is made of multiple layers where sensors, electrodes and connections are located.

1.3

D3 relates to wearable patient monitoring systems using knitted structures comprising strain gauges (D3, p. 2, section 2 'Significance of knitting technology'). Thus, D3 relates to

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (SEPARATE SHEET)

PCT/EP2004/053251

the same general subject as the application (p. 3, l. 7 - 12) and D1 (abstract). Furthermore, D3 discloses that advantageously such a knitted structure is composed of multiple layers (D3, p. 2, section 2 'Significance of knitting technology', last paragraph). Consequently, the skilled person would regard it as obvious to include this feature known from D3 in a device according to D1 in order to solve the problem posed.

The subject-matter of claim 1 can therefore not be considered as involving an inventive step (Article 33(3) PCT).

Since D1 also refers to detecting breathing pattern (section II, second sentence) and breathing signals are related to movement, claim 17 also lacks an inventive step (Article 33(3) PCT).

1.4

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 16, 18, and 19 does not involve an inventive step in the sense of Article 33(3) PCT.

1.5

With regard to claim 16, D1 refers to monitoring activity, ECG, and breathing pattern (section II, first para.). For the man skilled in the art, breathing patterns obviously include breathing activity and respiratory frequency. Thus, claim 16 discloses in addition to what is known from D1 detection of EOG and EMG signals. However, the man skilled in the art known about these signals and according to circumstances, would use the known fabric according to D1 and D3 for the detection of EOG and EMG signals without applying an inventive step.

1.6

With regard to claim 18, the same arguments, mutatis mutandis, as for claim 16 apply. Impedance pneumography is well known in the art and would obviously applied by the man skilled in the art.

1.7

With regard to claim 19, a double-bed jersey technique is a well known technique in the

field of knitting (see also D2, Example 13) and cannot support an inventive step.

1.8

Thus, claims 16, 18, and 19 lack an inventive step (Article 33(3) PCT).

2. Dependent claims

- 2.1
- Claims 12, 13, and 15 do not comply with the requirements of Rule 6.2 PCT since they refer to the drawings.
- 2.2

The features of claim 14 are obvious in view of D1 (section 'Conclusion') since 'cut and sew' is a standard textile industrial process.

2.3

Dependent claims 2 - 11, 20, 21 do not appear to contain any additional features which, in combination with the features of any claim to which they refer, meet the requirements of the EPC with respect to inventive step, since they are either disclosed by D1 or D3, or rendered obvious by the prior art (see passages cited in the search report).

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NEW SET OF CLAIMS

INPIBREC'S PCT/PTO U1 JUN 2006

- Knitted fabric wherein piezoresistive sensors for the monitoring of movement and breathing, electrodes for the monitoring of cardiac activity and breathing, and conductive connections for the transmission of signals are integrated, characterised in that said knitted fabric is made of multiple layers where sensors, electrodes and connections are located.
- Knitted fabric according to claim 1 wherein said piezoresistive sensors are realised by
 regions of fabric made of piezoresistive yarns.
 - 3. Knitted fabric according to claim 1-2 wherein said piezoresistive sensors are realised by the so-called "intarsia" technique.
- 4. Knitted fabric according to claim 1-3 wherein said electrodes and said conductive connections are realised by conductive yarns.
 - 5. Knitted fabric according to claim 1-4 wherein said electrodes and said conductive connections are made using the so-called "tubular intersia technique".
 - 6. Knitted fabric according to claim 1-5 wherein said electrodes are made of metal yarns twisted with standard yarns.
- 7. Knitted fabric according to claim 1-6 wherein said piezoresistive yarns are elastic yarns composed by electro-conductive fibres or synthetic fibres containing dispersed phases or shells of conductive materials.
 - 8. Knitted fabric according to claim 1-7 wherein said piezoresistive yarns are made with a lycra-based fabric coated with carbon loaded rubber.
 - 9. Knitted fabric according to claim 1-8 wherein said conductive connections are made of metal yarns twisted with standard yarns.
- 10. Knitted fabric according to claim 1-9 wherein said knitted fabric is made using the double-bed jersey technique.





11. Knitted fabric according to claim 1-10 wherein said knitted fabric is made of multiple layers in a way that electrodes are placed in contact with the skin of the user under examination while connections are insulated by a layer of fabric which separates them from the user's body.

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12. Knitted fabric according to claim 1-11 wherein said piezoresistive sensors and said electrodes are located as reported on figure (1).

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13. Knitted fabric according to claim 1-11 wherein said electrodes are located as reported on figure (6).

14 Knitted f

14. Knitted fabric according to claim 1-12 wherein said knitted fabric is employed in cut and sewn clothes and garments.

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15. Knitted fabric according to claim 13 wherein the sleeves comprised in said clothes and garments have a shape that is cut from said fabric, rotated with respect to knitting direction so that course in said sleeves are parallel to arm length.

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16. Use of the knitted fabric according to claim 1 - 15 for the detection of signals related to ECG, EOG, EMG, respiratory activity and respiratory frequency.

17. Use of the knitted fabric according to claim 1 - 15 for the detection of signals related to movement activity.

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18. Use of the knitted fabric according to claim 1 - 15 for the detection of impedance pneumography.

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19. Process for the production of a knitted fabric according to claim 1-15 wherein said knitted fabric is made using the double-bed jersey technique.

γ

20. Process according to claim 19 wherein said electrodes and said conductive connections are made using the so-called "tubular intersia technique".

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21. Process according to claim 20 wherein said knitted fabric is made with double bed weft knitting machines.



